

JUL - 7 2009

Zodiac® Polyaxial Spinal Fixation System
510(k) SUMMARY
April 2009

Company: Alphatec Spine, Inc.
5818 El Camino Real
Carlsbad, CA 92008
Direct: (760) 494-6769
Fax: (760) 431-0289

Contact Person: Paula Morgan, Regulatory Affairs Sr. Director

Trade/Proprietary Name: Zodiac® Polyaxial Spinal Fixation System

Common Name: Pedicle Screw Spinal Device

Classification Names: Spinal Interlaminar Fixation Orthosis
Pedicle Screw Spinal System

Classification Number(s)/Product Code(s): 21 CFR 888.3050, 888.3070
KWP, MNI, MNH

Product Description:

The Zodiac® Polyaxial Spinal Fixation System is intended for use as a posterior spinal fixation device to aid in the surgical correction of various spinal deformities and pathologies in the thoracolumbo-sacral iliac portion of the spine. It is intended to provide stabilization during the development of fusion utilizing a bone graft. Specific indications for the Zodiac® Polyaxial Spinal Fixation System are dependent in part on the configuration of the assembled device and the method of attachment to the spine.

Indications for Use:

The Zodiac® Polyaxial Spinal Fixation System is intended for use as a posterior spinal fixation device to aid in the surgical correction of various spinal deformities and pathologies of the spine. It is intended to provide stabilization during the development of fusion utilizing a bone graft. Specific indications for the Zodiac® Polyaxial Spinal Fixation System are dependent in part on the configuration of the assembled device and the method of attachment to the spine.

It is intended that this device, in any system configuration, be removed after development of solid fusion mass. Hook component indications are limited to T7-L5. Sacral-iliac screw indications are limited to the sacrum-iliac crest only.

1. The Zodiac® Polyaxial Spinal Fixation System when used as a hook and sacral iliac screw fixation system (nonpedicle screw) is intended for:
 - a. Patients having fractures of the thoracic and lumbar spine,
 - b. Patients having deformity (i.e. idiopathic scoliosis, neuromuscular scoliosis or kyphoscoliosis with associated paralysis or spasticity),
 - c. Patients having spondylolisthesis (i.e. isthmic spondylolisthesis, degenerative spondylolisthesis, and acute pars fracture allowing spondylolisthesis).
2. The Zodiac® Polyaxial Spinal Fixation System, when used a pedicle screw system in the thoraco-lumbo-sacral iliac region of the spine is intended for degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudoarthrosis).
3. In addition, the Zodiac® Polyaxial Spinal Fixation System, when used as a pedicle screw system is intended for:
 - a. Patients receiving only autogenous bone graft
 - b. Patient having the device fixed or attached to the lumbar and sacral iliac spine and having severe spondylolisthesis grade 3 or 4 at the fifth lumbar-first sacral (L5-S1) vertebral joint.
4. The Zodiac® Polyaxial Spinal Fixation System, when used as a laminar hook and bone screw system is intended for:
 - a. Patients having fractures of thoracic and lumbar spine.
 - b. Patients having thoracolumbar deformity (i.e. idiopathic scoliosis, neuromuscular scoliosis, kyphoscoliosis or kyphoscoliosis with associated paralysis or spasticity),
 - c. Patients having spondylolisthesis (i.e. Isthmic spondylolisthesis, degenerative spondylolisthesis and acute pars fracture allowing spondylolisthesis).

Substantial Equivalence:

The Zodiac® Polyaxial Spinal Fixation System additional components are substantially equivalent to the following predicate device:

<u>Trade/Proprietary/Model Name</u>	<u>Manufacturer</u>	<u>510(k) No.</u>
Zodiac® Polyaxial Spinal Fixation System	Alphatec Spine, Inc.	K033090
Zodiac® Polyaxial Spinal Fixation System	Alphatec Spine, Inc.	K042673
Zodiac® Stainless Steel Spinal Fixation System	Alphatec Spine, Inc.	K051286
Zodiac® 4.0 Polyaxial Spinal Fixation System	Alphatec Spine, Inc.	K071890

Performance Data:

Mechanical and dynamic testing was performed which provides reasonable assurance of safety and effectiveness for its intended use. Performance testing was performed per the recognized consensus standards and per the guidance document, Spinal System 510(k)s - Guidance for Industry and FDA Staff. This testing documented both static and fatigue performance characteristics. This testing clearly demonstrated that the performance characteristics satisfy the requirements of posterior lumbar fixation. The mechanical performance of the Zodiac® Polyaxial Spinal Fixation System additional components is substantially equivalent to the predicate Zodiac® Polyaxial Spinal Fixation System device. It is similar in terms of general design, intended use, and technological characteristics to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Alphatec Spine, Inc.
c/o Ms. Cheryl Joy Allen
Submissions Specialist – Regulatory Affairs
5818 El Camino Real
Carlsbad, California 92008

JUL - 7 2009

Re: K090779

Trade/Device Name: Zodiac® Polyaxial Spinal Fixation System

Regulation Number: 21 CFR 888.3070

Regulation Name: Pedicle screw spinal system

Regulatory Class: II

Product Code: MNI, MNH, KWP

Dated: June 4, 2009

Received: June 9, 2009

Dear Ms. Allen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

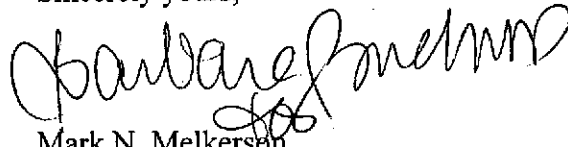
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Ms. Cheryl Joy Allen

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkersen", is written over the typed name.

Mark N. Melkersen

Director

Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**Indications for Use**

510(k) Number (if known): K090779

Device Name: Zodiac® Polyaxial Spinal Fixation System

Indications for Use:

The Zodiac® Polyaxial Spinal Fixation System is intended for use as a posterior spinal fixation device to aid in the surgical correction of various spinal deformities and pathologies of the spine. It is intended to provide stabilization during the development of fusion utilizing a bone graft. Specific indications for the Zodiac® Polyaxial Spinal Fixation System are dependent in part on the configuration of the assembled device and the method of attachment to the spine.

It is intended that this device, in any system configuration, be removed after development of solid fusion mass. Hook component indications are limited to T7-L5. Sacral-iliac screw indications are limited to the sacrum-iliac crest only.

1. The Zodiac® Polyaxial Spinal Fixation System when used as a hook and sacral iliac screw fixation system (nonpedicle screw) is intended for:

- a. Patients having fractures of the thoracic and lumbar spine,
- b. Patients having deformity (i.e. idiopathic scoliosis, neuromuscular scoliosis or kyphoscoliosis with associated paralysis or spasticity),
- c. Patients having spondylolisthesis (i.e. isthmic spondylolisthesis, degenerative spondylolisthesis, and acute pars fracture allowing spondylolisthesis).

2. The Zodiac® Polyaxial Spinal Fixation System, when used as a pedicle screw system in the thoraco-lumbo-sacral iliac region of the spine is intended for degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudoarthrosis).

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090779

510(k) Number _____



3. In addition, the Zodiac® Polyaxial Spinal Fixation System, when used as a pedicle screw system is intended for:

- a. Patients receiving autograft or allograft bone.
- b. Patient having the device fixed or attached to the lumbar and sacral iliac spine and having severe spondylolisthesis grade 3 or 4 at the fifth lumbar-first sacral (L5-S1) vertebral joint.

4. The Zodiac® Polyaxial Spinal Fixation System, when used as a laminar hook and bone screw system is intended for:

- a. Patients having fractures of thoracic and lumbar spine.
- b. Patients having thoracolumbar deformity (i.e. idioscoliosis, neuromuscular scoliosis, kyphoscoliosis or kyphoscoliosis with associated paralysis or spasticity),
- c. Patients having spondylolisthesis (i.e. Isthmic spondylolisthesis, degenerative spondylolisthesis and acute pars fracture allowing spondylolisthesis).

Prescription Use X
(Part 21 CFR 801 Subpart D)

OR

Over-The Counter Use _____
(Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

 (EXT for MKM)
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090779